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Cocaine Vaccine Shows Promise for Treating Addiction

NIDA Study Suggests Harnessing the Immune System Against Cocaine Addiction May Prove Effective

Immunization with an experimental anti-cocaine vaccine resulted in a substantial reduction in cocaine use in 38 percent of vaccinated patients in a clinical trial supported by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health. The study, published in the October issue of *Archives of General Psychiatry*, is the first successful, placebo-controlled demonstration of a vaccine against an illicit drug of abuse.

“The results of this study represent a promising step toward an effective medical treatment for cocaine addiction,” said NIDA Director Dr. Nora Volkow. “Provided that larger follow-up studies confirm its safety and efficacy, this vaccine would offer a valuable new approach to treating cocaine addiction, for which no FDA-approved medication is currently available.”

Like vaccines against infectious diseases such as measles and influenza, the anti-cocaine vaccine stimulates the immune system to produce antibodies. Unlike antibodies against infectious diseases, which destroy or deactivate the disease-causing agents, anti-cocaine antibodies attach themselves to cocaine molecules in the blood, preventing them from passing through the blood-brain barrier. By preventing the drug’s entry into the brain, the vaccine inhibits or blocks the cocaine-induced euphoria.

This study included 115 patients from a methadone maintenance program who were randomly assigned to receive the anti-cocaine vaccine or a placebo (inactive) vaccine. Participants were recruited from a methadone maintenance program because their retention rates are substantially better than programs focused primarily on treatment for cocaine abuse. Participants in both groups received five vaccinations over a 12-week period and were followed for an additional 12 weeks. All participants also took part in weekly relapse-prevention therapy sessions with a trained substance abuse counselor, had their blood tested for antibodies to cocaine, and had their urine tested three times a week for the presence of opioids and cocaine.

Participants differed in the levels of antibodies generated in response to vaccination. Thirty-eight percent attained blood levels of anti-cocaine antibodies thought to be sufficient to block

cocaine's euphoric effects. During weeks 9 to 16 (when antibody levels peaked), these participants had significantly more cocaine-free urines than those who received the placebo or those with active vaccine but low levels of anti-cocaine antibodies. Participants with the highest antibody levels had the greatest reductions in cocaine use. No serious adverse effects were associated with vaccine treatment.

"Fifty-three percent of participants in the high-antibody group were abstinent from cocaine more than half the time during weeks 8 to 20, compared with only 23 percent of participants with lower levels of antibodies," said Thomas Kosten, M.D., of Baylor College of Medicine in Houston, the study's principal investigator.

"In this study immunization did not achieve complete abstinence from cocaine use," added Dr. Kosten. "Previous research has shown, however, that a reduction in use is associated with a significant improvement in cocaine abusers' social functioning and thus is therapeutically meaningful."

Dr. Kosten led the study in collaboration with colleagues from Yale University School of Medicine, the Connecticut Veterans Administration (VA) Healthcare System, Baylor College of Medicine, and the Michael E. DeBakey VA Medical Center.

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The National Institute on Drug Abuse is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. The Institute carries out a large variety of programs to inform policy and improve practice. Fact sheets on the health effects of drugs of abuse and information on NIDA research and other activities can be found on the NIDA home page at www.drugabuse.gov. To order publications in English or Spanish, call NIDA's new *DrugPubs* research dissemination center at 1-877-NIDA-NIH or 240-645-0228 (TDD) or fax or email requests to 240-645-0227 or drugpubs@nida.nih.gov. Online ordering is available at <http://drugpubs.drugabuse.gov>. NIDA's new media guide can be found at <http://drugabuse.gov/mediaguide/>.

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